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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,037	09/17/2003	Richard D. Guarino	P-6186	2610
32330	7590	10/25/2005	EXAMINER	
DAVID W. HIGHET, VICE PRESIDENT AND CHIEF IP COUNSEL 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			AFREMOVA, VERA	
		ART UNIT	PAPER NUMBER	
		1651		
DATE MAILED: 10/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/664,037	GUARINO ET AL.
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 September 2003.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-57 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-57 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-57 (original claims on pages 18-24) are pending and subject to restriction requirement.

Please, note that there are 2 claims with number 57 (claims 57 on page 23 and claim 57 on page 24) and that claim 56 (original claim 56 on page 24) has tying error as related to claim dependency.

### ***Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16 and claim 57 (original claim 57 on page 24), drawn to a method for attaching and incubating liver cells in the presence of a cell adhesion promoting surface comprising CAR, ECM and an optional active factor, classified in class 435, subclass 395, for example.
- II. Claims 17-28 and claim 56 (original claim 56 on page 24), drawn to a cell culture of liver cells, classified in class 435, subclass 370, for example.
- III. Claims 29-34, drawn to a method for screening test agent effect on liver cells, classified in class 435, subclass 4, for example.
- IV. Claims 35 and 36, drawn to a method of making an ECM-modified composition for cell attachment comprising CAR, ECM and an optional active factor, classified in class 514, subclass 2+, for example.
- V. Claims 37-52, drawn to an ECM-modified composition comprising CAR and ECM, classified in class 514, subclass 2+, for example.

- VI. Claim(s) 53, drawn to a method for attaching cells to an ECM-modified composition comprising CAR and ECM, classified in class 435, subclass 325+, for example.
- VII. Claim(s) 57 (original claim 57 on page 23), drawn to a method for attaching and maintaining liver cells in the presence of a surface comprising CAR, collagen I and poly-L-ornithine, classified in class 435, subclass 370, for example.
- VIII. Claim(s) 54 (original claim 54 on page 23), drawn to a method for attaching and maintaining liver cells in the presence of a surface comprising CAR, collagen IV and poly-L-ornithine, classified in class 435, subclass 370, for example.
- IX. Claim(s) 55 (original claim 55 on page 24), drawn to a method for attaching and maintaining liver cells in the presence of a surface comprising CAR, collagen IV and elastin, classified in class 435, subclass 370, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the liver cells can be cultured and functionally maintained in sandwich cultures, for example: see abstract US 6,780,580.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a method for screening test agent effect on liver can be practiced by using hepatocyte sandwich cultures, for example: see abstract US 6,780,580.

Invention II and Invention V are two distinct products such as liver cells cultures and ECM chemical compositions.

Invention V and Inventions IV are distinct because they encompass products and making products wherein the claimed products have different compositions as claimed. Active factor is not required for the product of group V.

Inventions I and VI are drawn to distinct methods because they encompass attaching and maintaining different cells as claimed. The liver cells of group I method are not required for practicing the group VI method.

Inventions VII, VIII and IX are drawn to distinct methods of culturing liver cells because they required the use of different materials as claimed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention (one from the groups I-IX above) to be examined even though the requirement be traversed (37 CFR 1.143).

*Election of species*

This application contains claims directed to the following patentably distinct species of the claimed invention: 1) different ECM materials; 2) different CAR materials; and 3) different active factor materials.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are considered generic since none of the claims is limited to specific combination(s) of each 3 species of intended materials.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of species (ECM material and CAR material and factor material) to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

October 23, 2005



VERA AFREMOVA

PRIMARY EXAMINER